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JUL 18 1994

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Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,588,585

### NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,588,585 issued May 13, 1986, which claims the human drug product Betaseron, is eligible for patent term extension under 35 USC § 156. The period of extension has been determined to be 1,516 days.

The period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of January 4, 1994. Under 35 USC § 156(c):

$$\begin{aligned}\text{Period of Extension} &= 1/2 (\text{Testing Phase}) + \text{Approval Phase} \\ &= 1/2 (2,230) + 401 \\ &= 1,516 \text{ days}\end{aligned}$$

Since the regulatory review period began May 19, 1983, before the patent issue date, only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period. The period of time from the start of the regulatory review period on May 19, 1983, up to the issuance of the patent on May 13, 1986, is 1,089 days. This period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period:  $3,319 - 1,089 = 2,230$  days. No determination of a lack of due diligence was made.

The limitation of 35 USC § 156(g)(6) and the 14 year exception of 35 USC § 156(c)(3) do not operate to further reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue to the applicant for extension of the term of Patent No. 4,588,585 a certificate of extension, under seal, for a period of 1,516 days.

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Upon issuance of the certificate of extension the following information will be published in the Official Gazette:

U.S. Patent No.:	4,588,585
Granted:	May 13, 1986
Applicant:	David F. Mark et al.
Owner of Record:	Cetus Oncology Corporation
Title:	HUMAN RECOMBINANT CYSTEINE DEPLETED INTERFERON- $\beta$ MUTEINS
Classification:	424/85.2
Product Trade Name:	Betaseron
Term Extended:	1,516 days

C. E. Van Horn  
Charles E. Van Horn  
Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 11-44  
Rockville, MD 20857

RE: Betaseron  
FDA Docket No.: 93E - 0353